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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,144	07/06/2000	Wolfgang Neuberger	BJA170A	5264
7590 02/23/2006			EXAMINER	
Bolesh J Skutnik PhD JD 515 Shaker Road East Longmeadow, MA 01028			FARAH, AHMED M	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	09/611,144		NEUBERGER ET AL.	
	Examiner		Art Unit	
	Ahmed M. Farah		3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Note: the specification has the following minor informalities:

1. Page 1, line 18, recites "these scattering glasses ..." Correction, such as --scattering glasses-- is suggested.
2. Page 6, line 21, recites "surface in partially reflective ..." Correction such as --surface **is** partially reflective-- is suggested.
3. The numerical representation "**(205)**" in page 6, line 24, is believed to be a typographical error. Appropriate correction is required.

Claim Objections

(Presence of possible 112, sixth paragraph, limitations)

Claim 1-12 are objected to because of the following informalities: claim 1, line 4, recites the terms "means to homogenize/scatter;" claim 7 recites the term "means to deliver" in line 1; and claim 11 recites the term "means to homogenize/scatter" in line 6. It is not clear to the examiner whether the applicants want to invoke the 35 U.S.C. 112, sixth paragraph.

When it is not clear whether a claim limitation should be treated under 35 U.S.C. 112, sixth paragraph, determining the patentability of that claim is difficult because the scope of the claim and the relevance of the prior art cannot be readily determined. Applicants have an opportunity and obligation to define their inventions precisely during proceedings before the PTO. They are required to specify their inventions, consistent with the guidelines described in MPEP 2181, when a claim limitation invokes 35 U.S.C. 112, sixth paragraph.

A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for";
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the applicants wish to have the claim limitations under 112, sixth paragraph interpretation, they must: show why the claim language properly invokes 35 U.S.C. 112, sixth paragraph; identify the function; and identify the corresponding structure. They must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112, sixth paragraph. See *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Mersch US Patent No. 5,468,238.

Mersch discloses an endoscopic laser instrument comprising a diode laser disposed at the distal end of the instrument. The diode laser is powered remotely as recited in the instant claims

Mersch further teaches that the output radiation "can be at any selected wavelength and can be concentrated, diffused or have any other desired spatial distribution." See col. 7, lines 11-14.

With respect to claims 2-4, Mersch employs multimode diodes operating at different wavelengths (see col. 2, lines 48-54).

As to claim 6, he teaches a cooling mechanism 26 for cooling the radiation source. With respect to claim 11, the instrument is capable to perform the method steps as presently claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mersch in view of Berry US Patent No. 6,254,594.

Mersch, described above, does not teach the use of chemiluminescent material to provide the treatment radiation. However, the use of chemiluminescence to provide treatment light is known in the medical art. Berry discloses an alternative treatment device in which a chemical mixture is used to provide the treatment energy. Therefore, at the time of the applicant's invention, it would have been obvious to one skilled in the art to modify Mersch in view of Berry and use a chemiluminescence material as an equivalent alternative light source to provide the treatment energy.

Claims 6, 7, 9, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mersch in view of Chen et al. US Patent No. 5,800,478.

Mersch, described above, does not teach the use of a photoactive agent, centering balloon, or reflective coating.

Chen et al. disclose an alternative treatment device for insertion of a patient's body through incision to provide photodynamic therapy, the device comprising a remotely powered radiation source positioned at the distal end of the device (col. 19, lines 26-29). As to claim 7, Chen uses at least two photoactive agents to enhance the treatment (col. 18, lines 5-10). As to claim 9, Figure 14 depicts a balloon 170 disposed at the distal end of the treatment device. Chen et al also teach the use of reflective material disposed at the distal end of the treatment device.

Therefore, at the time of the applicant's invention, it would have been obvious to one skilled in the art to modify Mersch in view of Chen et al. and use photo-active agents to enhance the treatment. It would have been further obvious

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to use a balloon to position the treatment device within the treatment site. It would have been further obvious to use a reflective coating to homogenize the radiation from the source.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

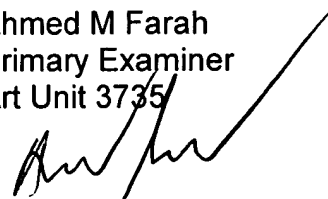
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on (571) 272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ahmed M Farah
Primary Examiner
Art Unit 3735



February 17, 2006.